510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:
k050500

B. Purpose for Submission:
Expansion of conditions under which the meter can be used including neonatal and arterial blood over a glucose range of 20-600 mg/dL. Over the counter use was 510(k) cleared in k992684.

C. Measurand:
Glucose

D. Type of Test:
Quantitative, Over-the-counter determination of glucose in whole blood.

E. Applicant:
TheraSense, Inc.

F. Proprietary and Established Names:
FreeStyle 600 Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1345: Glucose test system
   21 CFR 862.1660: Quality Control Material

2. Classification:
   Class II, Class I

3. Product code:
   NBW, CGA, JJX

4. Panel:
   (75) Chemistry

H. Intended Use:

1. Intended use(s):
   The FreeStyle 600 Blood Glucose Monitoring System is intended for in vitro diagnostic use for the quantitative measurement of glucose in fresh capillary, venous, arterial and neonatal whole blood samples. The FreeStyle 600 Blood Glucose Monitoring System is for testing outside the body (in vitro diagnostic use). The FreeStyle 600 Blood Glucose Monitoring System is intended for use in

the home and in professional settings to monitor blood glucose levels.

2. Indication(s) for use:
   The FreeStyle 600 Blood Glucose Monitoring System is intended for in vitro diagnostic use for the quantitative measurement of glucose in fresh capillary, venous, arterial and neonatal whole blood samples. The FreeStyle 600 Blood Glucose Monitoring System is for testing outside the body (in vitro diagnostic use). The FreeStyle 600 Blood Glucose Monitoring System is intended for use in the home and in professional settings to monitor blood glucose levels.

3. Special conditions for use statement(s):
   Over the counter use

4. Special instrument requirements:
   FreeStyle 600 Blood Glucose Test Strip, part of the FreeStyle 600 Blood Glucose Monitoring System, is only intended for use with the FreeStyle 600 Meter.

I. Device Description:

The FreeStyle 600 Blood Glucose System is an electrochemical biosensor consisting of a glucose-oxidizing enzyme on a disposable test strip (the electrochemical sensor) and a hand-held current measuring device. Software internal to the hand-held device converts the measured current into glucose concentration using an algorithm that depends on the ambient temperature and the activity of the enzyme on the test strip. The user has the ability to validate the operation of the system by using glucose control solutions provided with the system.

The devices used well established biochemical, electrical, and software methodologies. No new or unproven techniques are introduced with this device.

The FreeStyle 600 Blood Glucose Monitoring System comprises a glucose reagent test strip, a handheld meter, three quality control solutions, and an owner's booklet. A lancing device, lancets, a quick reference guide for performing the test, a logbook for recording test results, and a carry case are also included with the system.

The capabilities of the on-market FreeStyle Blood Glucose Monitoring System have been expanded, primarily through modification of the internal software, to measure glucose ranges from 20 to 600 mg/dL.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Freestyle Blood Glucose Monitoring System

2. Predicate 510(k) number(s):
   k992684

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Analyte	Glucose	Glucose
Measurement Method	Electrochemical	Electrochemical
Tested material	Whole Blood	Whole Blood
Enzyme	PQQ dependent glucose dehydrogenase	PQQ dependent glucose Dehydrogenase

Differences		
Item	Device	Predicate
Recommended Sample	Venous, capillary, arterial or neonatal whole blood	Venous or capillary whole blood
Measurement Range	20-600 mg/dL	20-500 mg/dL
Quality Control Material	Low, Normal, High	Normal

K. Standard/Guidance Document Referenced (if applicable):

Guidance for Industry: In Vitro Diagnostic Glucose Test System
Available at:
http://www.fda.gov/cdrh/ode/glucose.pdf

ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

L. Test Principle:

The FreeStyle 600 Blood Glucose System is an electrochemical biosensor consisting of a glucose-oxidizing enzyme on a disposable test strip (the electrochemical sensor) and a hand-held current measuring device. Software internal to the hand-held device converts the measured current into glucose concentration using an algorithm that depends on the ambient temperature and the activity of the enzyme on the test strip.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
   The precision of the system was confirmed using by performing multiple measurements on different manufacturing lots of strips and different meters. At a low glucose of 40 mg/dL, the system has a %CV of approximately 5% at a Hematocrit of 45%. This %CV roughly doubles for a Hematocrit of 65% at the same glucose concentrations. The precision of the system is better than 4% CV for both Hematocrit levels at a glucose concentration of 90 mg/dL.

   b. *Linearity/assay reportable range:*
   The company substantiated their equivalence claims with using a series of detailed studies comparing the performance of their device both to the predicate and a YSI glucose analyzer across the range of conditions claimed in

their indications for use. In particular, the company verified the performance of their system using high Hematocrit, high bilirubin samples over the entire glucose range of 20 to 600 mg/dL. Glucose measurements were also shown to be independent of temperature and anti-coagulants. Specifically, under extreme conditions, 90% of the data were in zone A of the Clarke Error grid and 10% of the results were in the B zone over the 20-600 mg/dL range of glucose concentrations.

From the results, the FreeStyle strips give clinically relevant results even in limiting conditions of hematocrit and temperature

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
The company supplies glucose control solutions to validate the performance of the meter. Control solutions are prepared gravimetrically. Stability is assessed via accelerated and ongoing real-time aging studies where the glucose concentrations are determined by measurement with the YSI glucose meter. Stability is evaluated as difference in glucose ≤5% for the time period. These measurements substantiate the claim of shelf life of 2 years if stored between 35 – 86 °F (2 – 30 °C).

d. *Detection limit:*
Not applicable

e. *Analytical specificity:*
The company conducted extensive interference studies examining the impact of EDTA, heparin, hematocrit, bilirubin, and temperature as part of the linearity studies (see b)., above). On their product, the impact of these interferences was minimal. Changes in measurement of the analyte, glucose, were within acceptable error over the full range of the glucose studies, 20 – 600 mg/dL.

In addition, the company specifically examined the impact of anticoagulants over a range of glucose concentrations. They did not observe a clinically relevant impact on the analyte measurement in samples containing coagulant concentrations up to four times those typically encountered in clinical samples.

f. *Assay cut-off:*
Not applicable

2. Comparison studies:
   a. *Method comparison with predicate device:*
   Not applicable

   b. *Matrix comparison:*
   Not applicable

3. Clinical studies:
   a. *Clinical Sensitivity:*
      Not applicable

   b. *Clinical specificity:*
      Not applicable

   c. Other clinical supportive data (when a. and b. are not applicable):

      To further substantiate their claim for neonatal use, the company performed a clinical study in addition to their laboratory evaluation of high hematocrit, high bilirubin blood. The company compared the performance of their candidate device, the FreeStyle 600 Blood Glucose Monitoring System, to a laboratory reference method. Duplicate measurements using multiple lots of strips lots were used to evaluated glucose in neonatal blood at one clinical site. A total of 194 samples were used in this study. The device under submission demonstrated a linear correlation with the laboratory reference with a slope of 1.04, intercept of -4.2 mg/dL and a correlation coefficient of 0.99. The concentration of the samples ranged from 29 to 185 mg/dL.

      To substantiate the claim for arterial blood, the company conducted a clinical study to compare the device under submission, FreeStyle 600 Blood Glucose Monitoring System, to a laboratory reference method. A YSI 2300 Plus glucose analyzer served as the comparator. Investigators at two clinical sites performed duplicate measurements of arterial blood using three different lots of strips. Three hundred and one patients participated in the study. The device under submission demonstrated a linear correlation with the laboratory reference with a slope of 1.06, intercept of -5.0 mg/dL and a correlation coefficient of 0.98.

4. Clinical cut-off:
   Not applicable

5. Expected values/Reference range:
   The package insert states 70 to 110 mg/dL as the reference range for fasting glucose for a non-diabetic adult. This range is based upon literature, Tietz Textbook of Clinical Chemistry, 2nd Edition, W.B. Saunders, Philadelphia. 1994.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports substantial equivalence decision.